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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/200,657      | 11/25/1998  | MICH B. HEIN         | TSRI-184.2CO        | 9640             |

7590 01/22/2002

FOLEY & LARDNER  
BARRY S. WILSON  
P.O. BOX 80278  
SAN DIEGO, CA 92138-0278

EXAMINER

BUI, PHUONG T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1638

DATE MAILED: 01/22/2002

28

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/200,657

Applicant(s)

HEIN ET AL.

Examiner

Phuong T. Bui

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 04 January 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See attached sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 21, 32-54, 56-66 and 68-82.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Phuong T. Bui  
Primary Examiner  
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1. The newly submitted amendment will not be entered since the new recitation that the light or heavy chain polypeptides or both are "not full length" raises both new issues with regard to whether the prior art renders obvious such a recitation and whether this change is new matter or not.

Regarding the new matter issue, a review of the portions of the original disclosure referenced by applicant reveals that whenever a fragment of the entire light or heavy chain polypeptide was being discussed, these fragments were specific fragments known in the art including the Fab and Fv fragments. The recitation "not full length" covers fragments of the light or heavy chain polypeptides that have as much as one less amino acid residue as the full-length polypeptide. The original disclosures reference to fragments or portions of the light and heavy chain polypeptides would have been interpreted by one of skill in the art to cover the functionally known fragments of these polypeptides only, not any polypeptide from one amino acid to one less than the full length polypeptide. Note that later claims specifically recite these fragments as Fab, Fab', F(ab')<sub>2</sub> and Fv, all of which are disclosed and known in the art. Accordingly, the Office concludes that the amendment includes new matter and cannot be entered.

In addition, because the scope of the term "not full length" encompasses every fragment of the light and heavy chain polypeptides from one amino acid to one less than the full-length amino acid, the issue of whether such a recitation would have been obvious to one of ordinary skill in the art has not been specifically addressed. Accordingly, this matter would require further consideration and search.

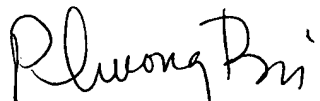
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In addition, the exclusionary language added to claim 43 that cells containing nucleotide sequence encoding an immunoglobulin heavy chain polypeptide do not contain nucleotide sequence encoding an immunoglobulin light chain polypeptide and vice versa is a new limitation not previously presented and raises new issues with regard to search and consideration. Even if such a limitation defined over the prior art of record, the Office has not addressed the issue of whether such a limitation would have been obvious to one of ordinary skill in the art. Accordingly, these new limitations are deemed to raise new issues warranting non-entry of Applicant's after-final amendments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 703-305-1996. The examiner can normally be reached on 6:30 AM - 4:00 PM; Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Phuong T. Bui  
Primary Examiner  
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